

State of Iowa  
**Board of Pharmacy**

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**BOARD MEMBERS**

BRETT BARKER  
GAYLE MAYER  
DANE NEALSON  
KATHRYN STONE

JASON HANSEL

*Board Chair*

ANDREW FUNK

*Executive Director*

**BOARD MEMBERS**

LADONNA GRATIAS  
EDWARD MCKENNA  
JOAN SKOGSTROM

**TELECONFERENCE MEETING MINUTES**

**October 3, 2019**

The special meeting of the Iowa Board of Pharmacy was held on Thursday, October 3 2019, at 11:00 a.m., via teleconference pursuant to the provisions of Iowa Code section 21.8. An in-person meeting was impractical due to the timely nature of agenda items and the anticipated brevity of the meeting. Several members of the public called in. Jason Hansel called the meeting to order at 11:01 a.m.

**MEMBERS PRESENT**

Jason Hansel, Chair  
Edward J. McKenna, Vice-Chair  
Brett Barker  
LaDonna Gratias  
Gayle Mayer  
Kathy Stone  
Joan Skogstrom

**STAFF PRESENT**

Andrew Funk, Executive Director  
Laura Steffensmeier, Esq., Assistant Attorney General  
Therese Witkowski, Executive Officer  
Amanda Woltz, Administrative Assistant  
Sue Mears, Compliance Officer  
Christie Carlson, Compliance Officer  
Jean Rhodes, Compliance Officer

**MEMBERS ABSENT**

Dane Nealson

**AGENDA**

Discussion and vote regarding the enforcement of compliance with USP <795>, <797>, <800>, and <825>.

On a motion by Kathy Stone, seconded by Brett Barker the Board voted unanimously by roll call vote to approve the following:

*Enforcement of USP Chapter 800*

- All pharmacies are expected to be fully compliant with USP Chapter 800 beginning on December 1, 2019. This includes pharmacies that receive, store, handle, dispense, or compound hazardous drugs.

*USP Chapters 795 and 797: Current Versions v. Proposed Revisions*

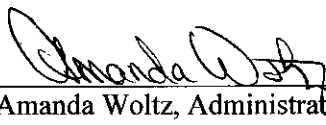
- A pharmacy that has made progress towards complying with the proposed revisions to USP Chapters 795 and 797 will not be penalized for doing so. A pharmacy that is already compliant or making progress towards compliance with the proposed revisions will have a head start at achieving compliance by the new effective date, which will be established by USP.
- During this period of flux, a pharmacy may comply with either the current versions or the proposed revisions of USP Chapters 795 and 797. A pharmacy is expected to establish and follow standard operating procedures for sterile and nonsterile compounding which identify the version of USP Chapters 795 or 797 it intends to follow. Requirements specified by USP Chapter 800 must be followed for hazardous compounding even if not specified by current versions of USP Chapters 795 or 797, unless a delayed compliance petition has been granted.
- All compounding pharmacies will be expected to comply with the proposed revisions to USP Chapters 795 and 797 by the effective date established by USP, which has yet to be determined.

*Delayed Compliance Petitions*

- Board rule 657—8.5(11) establishes a process whereby a pharmacy engaged in compounding of hazardous drugs may request delayed compliance for specific requirements of USP Chapter 800 pertaining to compounding in accordance with rule 657—20.5. The Board has received and responded to several petitions filed under these provisions.
- A compounding pharmacy that can comply with all requirements of USP Chapter 800 by December 1, 2019 does not need to submit a petition for delayed compliance. A pharmacy is not eligible to receive delayed compliance for any non-compounding requirements in USP Chapter 800.
- A compounding pharmacy that has been granted a delay in compliance will retain the delay as specified in the approval letter. The granted delay will be valid through the end date referenced in the approval letter.

Motion by Gayle Mayer, seconded by Joan Skogstrom, to adjourn at 11:48 a.m. on October 3, 2019. Motion was approved by voice vote.

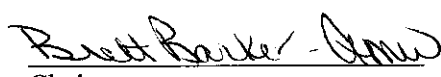
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Amanda Woltz, Administrative Assistant and Recording Secretary



Andrew Funk  
Executive Director



Chairman

APPROVED THIS 5<sup>th</sup> DAY OF November, 2019